

CLAIMS: Clean version under 37 C.F.R. 1.121(c)(1)(i)

- B2
Sub A
1. (Amended) A method of pipelining a disease-specific diagnostic algorithm to achieve a cost-effective and accurate diagnosis, said method comprising the steps of:
 - a) classifying the various subgroups of the disease, said subgroups being classified based on pathology, pathogenic agent, cause or symptoms, on an n-bit data word stored in a memory;
 - b) defining the clinical tests suitable for confirming the diagnosis of each of the subgroups classified in a);
 - c) selecting to run the clinical tests listed in b) for the sub-group showing some abnormality and comparing the result with the normal value provided on the n-bit data word;
 - d) sequentially running the relevant clinical test of each of the sub-groups upon receiving a first of said clinical test values, and computing the next set of said clinical test for further testing, and
 - e) repeating steps c) and d) until a complete diagnosis of the specific disease type and group is provided, thereby avoiding unnecessary clinical tests and expensive duplicative procedures, while enabling an accurate diagnosis using the disease-specific diagnostic algorithm.

2. (Amended) The method of claim 1, further comprising performing a different clinical test after the value for the last clinical test is negative, to rule out a different diagnosis.

3. (Amended) The method of claim 1, further comprising using a program code to implement the diagnostic algorithm.

4. (Amended) The method of claim 3, further comprising using a modified computer architecture code to implement any modifications in the diagnostic algorithm.

5. (Amended) The method according to claim 1, where said method is the acid fast bacteria algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of acid-fast bacteria;
- b) defining each of the clinical tests listed in (a) on the n-bit data word and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values of the n-bit data word from said memory;
- d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values includes auramine smear and the next set of said clinical tests includes amplification; and

- SUB E1*
- e) receiving a next one of said clinical test of said data word,
wherein the next of said clinical tests includes organism
identification by DNA probe or biochemicals.

6. (Amended) The method according to claim 1, wherein said method is
the anemia algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of anemia, including myelodysplasia, leukemia, iron deficiency, or B-12/folate deficiency;
- b) defining each of the clinical tests listed in (a) on the n-bit data word and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values of the n-bit data word from said memory; and
- d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include WBC, MCV, ferritin, B12/folate and the next set of said clinical tests includes smear/image or reticulocyte count, hemoglobin ID, B-12 or folate respectively.

B2
B

7. (Amended) The method according to claim 1, wherein said method is
the cardiac risk algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of cardiac risk, including abnormalities in cholesterol, triglycerides, LDL, HDL, homocysteine or anti-cardiolipin;
- b) defining each of the clinical tests listed in (a) on the n-bit data word and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values of the n-bit data word from said memory; and
- d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include cholesterol, HDL, triglycerides and the next set of said clinical tests includes homocysteines anticardio- lipin antibody, LDL by calculation or LDL by direct assay.

8. (Amended) The method of claim 1, wherein said method is the HbsAg algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of HbsAG;
- b) defining each of the clinical tests listed in (a) on the n-bit data word and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values of the n-bit data word from said memory; and

- d) upon receiving a first of said clinical test values, computing the next set of said clinical test for further testing, wherein the first of said clinical test values include prenatal and dialysis specimen measurements of hepatitis B.

9. (Amended) The method according to claim 1, wherein said method is the breast cancer algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of breast cancer including genetic markers;
- b) defining each of the clinical tests listed in (a) on the n-bit data word and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values of the n-bit data word from said memory; and
- d) upon receiving a first of said clinical test values, computing the next set of said clinical test for further testing, wherein the first of said clinical test values include cancer marker 15-3, or cancer marker 27-29 and the next set of said clinical tests includes serum bone marker.

10. (Amended) The method according to claim 1, wherein said method is the prostate cancer algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of prostate cancer including PSA for no risk, equivocal risk or positive cancer;
- b) defining each of the clinical tests listed in (a) on the n-bit data word and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values of the n-bit data word from said memory; and
- d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing wherein the first of said clinical test values include PSA (total) and the next set of said clinical tests includes free PSA or serum bone marker.

11. (Amended) The method according to claim 1, wherein said method is the Epstein-Barr virus algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of Epstein-Barr virus, including viral capsid antigen, or Epstein Barr-Virus;
- b) defining each of the clinical tests listed in (a) on the n-bit data word and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values of the n-bit data word from said memory; and

- B2
- d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing wherein the first of said clinical test values include anti-EBV early antigen D, and the next set of said clinical tests includes anti VCA and EBNA.

B3 Sub B
E1

13. (Amended) The method according to claim 1, wherein said method is the thyroid function algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of thyroid dysfunction;
- b) defining each of the clinical tests listed in (a) on the n-bit data word and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values of the n-bit data word from said memory;
- d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include TSH and the next set of said clinical tests includes FT-3 or FT-4.

14. (Amended) The method according to claim 1, wherein said method is the autoimmune algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of autoimmune disease including lupus;

- b) defining each of the clinical tests listed in (a) on the n-bit data word and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values of the n-bit data word from said memory;
- d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include ANA and the next set of said clinical tests includes ds-DNA, HISTONE, Sm respectively, and
- e) receiving a next one of said clinical test of said data word, wherein the next of said clinical tests includes SCL-70, RNP, SSA, SSB, SS-DNA.

15. (Amended) The method according to claim 1, wherein said method is the serum protein algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of serum protein defect including serum protein electrophoresis;
- b) defining each of the clinical tests listed in (a) on the n-bit data word and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values of the n-bit data word from said memory; and

- d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include serum immuno fixation electrophoresis and the next set of said clinical tests includes quantitative assay of immuno globulin identified by SIFE.

16. (Amended) The method according to claim 1, wherein said method is the urinalysis algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis urine abnormalities;
- b) defining each of the clinical tests listed in (a) on the n-bit data word and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values of the n-bit data word from said memory; and
- d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include protein, blood, leukocyte esterase ornitrite and the next set of said clinical tests includes microscopic examination of urine.

17. (Amended) The method according to claim 1, wherein said method is the human immunodeficiency algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of human immunodeficiency virus;
- b) defining each of the clinical tests listed in (a) on the n-bit data word and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values of the n-bit data word from said memory;
- d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include HIV-1 and the next set of said clinical tests includes HIV-1 and HIV-2 respectively, and
- e) receiving a next one of said clinical test of said data word, wherein the next of said clinical tests includes HIV-2 WB.

18. (Amended) The method according to claim 1, wherein said method is the hepatitis B algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of hepatitis B, including HBsAg, HBsAb or SGPT;
- b) defining each of the clinical tests listed in (a) on the n-bit data word and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values of the n-bit data word from said memory;

- d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include HBsAg(+), HBsAg(-)/HBsAb(+) or HBsAg(-)/HBsAb(-), and the next set of said clinical tests includes AFP/HBeAg/Ab, Immune or Hepatitis B(-) respectively;
- e) receiving a next one of said clinical test of said data word, wherein the next of said clinical tests includes "Is HBe Ab present?".
- f) computing a next portion of the diagnostic algorithm using said next of said clinical tests and a most recently calculated value of a computation of a prior portion of the diagnostic algorithm to produce a second clinical test value; and
- g) if necessary, repeating steps (e) and (f) until all of said clinical tests of the data word have been processed, wherein the final value computed for the last clinical test is a value for the complete diagnosis of hepatitis B.

19. (Amended) The method according to claim 1, wherein said method is the syphilis algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of syphilis;
- b) defining each of the clinical tests listed in (a) on the n-bit data word and providing the normal value of each clinical test;

- c) sequentially reading out each of said clinical test normal values of the n-bit data word from said memory; and
- d) upon receiving a first of said clinical test values, computing the next set of said clinical test for further testing, wherein the first of said clinical test values include Elisa for T. Pallidum, and the next set of said clinical tests includes repeat Elisa and the rapid plasma regain test.

20. (Amended) The method according to claim 1, wherein said method is the thrombophilia algorithm comprising the steps of:

- a) defining the clinical tests used for the diagnosis of thrombophilia including LA/APA Alg(+) or APC-R(+);
- b) defining each of the clinical tests listed in (a) on the n-bit data word and providing the normal value of each clinical test;
- c) sequentially reading out each of said clinical test normal values of the n-bit data word from said memory;
- d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include LA-APA Alg(+) or APC-R(+) and the next set of said clinical tests includes homocysteine CRP; and

3
3

e) receiving a next one of said clinical test of said data word,
wherein the next of said clinical tests includes Protein C, Protein
S or AT-11.

21. (Amended) An apparatus for pipelining a diagnostic algorithm on an
n-bit data word, said apparatus comprising:

- a) a memory storing component, said component used for storing
the n-bit data words relevant to a set of m clinical tests;
- b) means for sequentially reading out each of a m clinical tests of
the n-bit data from said memory, wherein m is an integer greater
than one;
- c) a processor for sequentially programming each of the m clinical
tests to produce a complete diagnosis, and for outputting the
result.

22. (Amended) The apparatus of claim 21, wherein the m clinical tests
have an equal number of bits.

23. (Amended) The apparatus of claim 21, wherein the memory
comprises an array of chips, each of which includes a plurality of m-bit
storage cells.

24. (Amended) The apparatus of claim 23, wherein m equals at least
one.

Sub C1

25.(new) The method according to claim 1, wherein said method is the lupus algorithm comprising the steps of:

- b4*
- a) defining the clinical tests for diagnosis of lupus anticoagulant/APA;
 - b) defining each of the clinical tests listed in (a) on the n-bit data word and providing the normal value of each clinical test;
 - c) sequentially reading out each of said clinical test normal values of the n-bit data word from said memory; and
 - d) upon receiving a first of said clinical test values, computing the next set of said clinical tests for further testing, wherein the first of said clinical test values include DRVFT and the next set of said clinical tests includes LAC.